PSJ3

Exhibit 57G

Patient Evaluation Tools: ~~Pain Inventory~~
Pain Assessment and Documentation Tool (PADT)

[video]
[link to downloadable PADT and PADT Guidebook PDFs]

Can developed to assist in the documentation of what have been called the "4 A's" — key outcomes of pain therapy:

Script

Patient Evaluation Tools: Pain Inventory

Pain Assessment and Documentation Tool (PADT)

Cell	Visual	Audio
101	Open with KTL onscreen. As he starts to list the 4As, cut to these words onscreen: **A**nalgesia **A**ctivity **A**dverse effects **A**berrant behavior [Make sure this text is at the bottom of the screen showing the 4As, in smaller type: Passik SD, Kirsh KL, Whitcomb L, et al. A new tool to assess and document pain outcomes in chronic pain patients receiving opioid therapy. *Clin Ther*. 2004;26:552-561.]	**Narrator:** The Pain Assessment and Documentation Tool (PADT) ~~is structured based on the "4 As" of pain medicine~~: analgesia, activity, adverse effects, and aberrant behavior.
102	KTL onscreen.	**Narrator:** The PADT was developed by Steven Passik and colleagues as a way to concentrate on key outcomes and offer a reliable way to record outcome ~~progress in pain management~~ therapy over the long term. It is generally used during follow-up visits after the initial evaluation, about once every 3 months.
103	Animation of first line of "Current Analgesic Regimen" section being filled out. This line should have the following text: **Drug name** Sample opioid **Strength** 2 mg **Frequency** 1x/day **Maximum dose** 2 mg	**Narrator:** First, fill out the Current Analgesic Regimen section with the drugs the patient is currently taking.
104	Animation showing the following: Analgesia section: 1. Circle "4" 2. Circle "6" 3. Write in "50%" 4. Check the "Yes" box	**Narrator:** An interview with the patient is used to complete the sections on analgesia, activities of daily living, and adverse events. This interview may be conducted by the examining physician, nurse, physician assistant, or nurse practitioner.

105	KTL onscreen.	**Narrator:** The sections on assessment and potential aberrant-related drug behavior must be completed by the examining physician either during or immediately following the patient visit.
106	Medium shot of first page of PADT Guidebook.	**Narrator:** For more information on how to use the PADT, please see the PADT Guidebook.

Patient Evaluation Tools: ~~Pain Inventory~~
Simple ~~Descriptive~~ Pain Intensity Scale

[video]
[link to downloadable Simple Descriptive Pain Intensity Scale PDF]

Script

Patient Evaluation Tools: ~~Pain Inventory~~

Simple ~~Descriptive~~ Pain Intensity Scale

There are many types of unidimensional pain intensity scales. Pain intensity should be assessed in a framework ("right now", "at its worst", and time frame if appropriate (e.g., last day or last week). For example,

Cell	Visual	Audio
101	Open with KTL onscreen. When he begins "is a figure…", switch to a view of the form, with a close-up of the scale. When he begins "It is easy", switch back to the KTL talking.	**Narrator:** The Simple Descriptive Pain Intensity Scale, developed by the Agency for Healthcare Policy and Research, is a figure showing a continuum of pain intensity from "No pain" to "Worst Possible Pain". It is easy to use and offers a simple assessment of intensity. ~~if there is no time to administer a longer form or if the patient would have trouble answering more complex questions~~.
102	Back to the form. Close-up of scale, then show animation of a circle being drawn around the "Very Severe Pain" bar.	**Narrator:** To use the scale, ask the patient to describe their pain as mild, moderate, severe, very severe, ~~or the worst possible~~. You can also show the form to the patient and ask them to point to the bar corresponding to their level of pain. Remember to provide a framework and a time frame for the question.

Patient Vignettes

Dr. Russell Portenoy has developed 4 questions that health care professionals should keep in mind when assessing patients with moderate-to-severe pain who may be candidates for a trial of long-term opioid therapy.

1. What is conventional practice? That is, what is the usual course of treatment for this type of pain?

2. Are there any other therapies with an equal or better therapeutic index?

3. What is the risk of adverse drug effects?

4. What is the risk of drug abuse, addiction, or diversion?

These questions should not only be asked at the initial evaluation, but throughout the entire course of opioid treatment. Also, it is important to keep in mind that opioid trials need to be structured differently for pain caused by acute or chronic conditions.

The links below will take you to vignettes illustrating real-life scenarios of low-, moderate-, and high-risk patients. In each one, you will see how the 4 questions and the risk and pain assessment tools listed in Section 3 of this resource are put to use in everyday practice.

[clickable button for Case]
[clickable button for Case]
[clickable button for Case]

Low-Risk Patient 1: Fran

Cell	Visual	Audio
101	On-screen text: Case Study: Fran • 79 years old; retired • Diagnosed with moderately severe OA of the right hip 5 years ago • Pain has worsened over the past few months • Orthopedist advised pharmacologic management plus physical therapy (PT) • Takes an NSAID daily, with little relief • Has regular PT sessions and does exercises at home, but has gotten limited benefit from them	**Narrator:** Fran is a 79-year-old retired postal worker. Five years ago, she began to experience hip pain on a daily basis and she subsequently received a diagnosis of moderately severe osteoarthritis of the right hip. During the past few months, her pain has progressively worsened. Her physician referred her to an orthopedist, who advised medical management and physical therapy. She is currently taking an NSAID daily, with little relief. Physical therapy has been of limited benefit, although she has been adherent to both office-based sessions and a home regimen.
102	On-screen text: • Pain severe enough that Fran has trouble walking or climbing stairs • Interferes with sleep	**Narrator:** Fran states that her hip pain is now so severe that she has trouble walking and climbing stairs. Her pain is not relieved by sitting or lying down and has begun to interfere with her sleep.
103	Animation of the first page of the Brief Pain Inventory being filled out. Zoom in on Question 5, and show a circle being drawn around the number 10. Do the same for Question 6. Provide a link at the bottom of the page to a PDF of the BPI.	**Narrator:** Using the Brief Pain Inventory, on a pain scale of 0 to 10, with 10 being the most severe, Fran rates both her overall pain and current pain as 10.
104	Show first page of the American Geriatrics Society 2009 article.	**Narrator**: In 2009, the American Geriatrics Society, or AGS, issued guidelines for the pharmacologic management of persistent pain in older persons. The guidelines recommend tailoring treatment plans for each patient and using the least-invasive method of drug administration. Mixing agents and combining pharmacologic and nonpharmacologic strategies are also

		treatment options.
105	Go to a close-up of page 1342 (page 12 in the PDF) of the American Geriatrics Society 2009 article. When the narrator begins to read "All patients with", zoom in on the Opioids section. Isolate and highlight Paragraph VIII.	**Narrator:** The AGS guidelines have this recommendation about opioid therapy in older persons: "All patients with moderate-to-severe pain, pain-related functional impairment, or diminished quality of life due to pain should be considered for opioid therapy."
106	Animation of Patient Version of the Opioid Risk Tool (ORT) being filled out. As the narrator reads the 2nd sentence, an animated pencil checks off the boxes marked "Family History of Substance Abuse—Alcohol".	**Narrator:** Fran's physician thinks she would be a good candidate for opioid therapy, so she gives her the Opioid Risk Tool to fill out. She explains that all patients who are prescribed opioids in her practice are asked similar questions to ensure that therapy can be structured to reduce potential harm to the patient. Fran says that she believes her father was an alcoholic, but she does not drink herself.
107	View switches to the Physician Version of the ORT. The same boxes that were checked off on in the last scene are already filled out here. As the narrator talks, the scores for each category, under the "Item score if female" column, are somehow highlighted (maybe isolated and enlarged)	**Narrator**: Based on Fran's family history of alcohol abuse, her score is 3, indicating a low risk for opioid abuse.
108	On-screen text: **How would you treat Fran?** a. Try a new NSAID or other pharmacologic agent b. Prescribe opioid therapy d. Prescribe opioids plus continue her on NSAIDs	**Narrator:** How would you proceed with treatment for Fran? • Try a new NSAID or other pharmacologic agent • Prescribe opioid therapy • Or, prescribe opioids plus continue her on NSAIDs
109	On-screen text: **Fran is prescribed a twice-daily course of low-dose opioid therapy**	**Narrator:** Fran is prescribed a twice-daily course of low-dose opioid therapy, and is asked to discontinue her current NSAID.
110	On-screen text: **At follow-up 2 weeks later**	**Narrator:** At the follow-up visit 2 weeks later, Fran states that her pain is now a 6 on the 0-10 rating scale,

	• Fran's pain has lessened—now a 6 out of 10 • Has constipation	although she is now suffering from constipation.
111	On-screen text: What would your next step be? a. Maintain current regimen b. Keep her on opioids and manage her side effects c. Discontinue opioid therapy and prescribe a different agent	**Narrator:** Given this information, what would your next step be? • Maintain Fran's current treatment regimen as is • Keep her on opioids • Or, discontinue opioid therapy and prescribe a different agent
112	On-screen text: Possible options for next steps • Keep her on opioids and manage her side effects	**Narrator:** Fran's physician should talk with her about the benefits and disadvantages about keeping her on opioid therapy. If Fran is pleased with the pain relief she is getting, or would like a greater reduction in pain, her physician can adjust the opioid dose and recommend taking a laxative to deal with the constipation.
113	On-screen text: Possible options for next steps • Discontinue opioid therapy and prescribe a different agent	**Narrator:** If Fran feels that the side effects are not worth the pain relief, or doesn't feel that opioids are right for her, her physician can discontinue the opioid therapy temporarily and prescribe another agent that Fran has not yet tried.
114	Show both pages of the PADT tool side by side. Provide a link at the bottom of the screen to PDFs of the PADT and the PADT Guidebook.	**Narrator:** Fran will continue her regular follow-up visits. At each visit, her physician will use the Physician Assessment and Documentation Tool, or PADT, to monitor her pain and adjust her therapy as needed.

Low-Risk Patient 2: Paul

Cell	Visual	Audio
101	On-screen text: **Case Study: Paul** • 41 years old • Severe ~~pain due to herniated disk~~ • Cannot sit for more than 20-minute stretches • Pain is interfering with work • Previous therapies included behavioral therapy, physical therapy, spinal injections, and NSAIDs, with varying degrees of efficacy • Nonsmoker and occasional drinker • Smoked marijuana a couple of times in college but hasn't used drugs since	**Narrator:** Paul is a 41-year-old man who comes to his physician's office in severe pain ~~from a previously diagnosed herniated disk~~. He is unable to tolerate sitting for more than 20 minutes without significant discomfort, which is interfering with his work. He has previously been treated with cognitive behavioral therapy, physical therapy, spinal injections, and NSAIDs, with varying degrees of efficacy. Paul does not smoke and only drinks occasionally. He smoked marijuana a couple of times in college, but has not used illegal drugs since then.
102	Medium shot of the Simple Descriptive Pain Intensity Scale tool, then close up on the scale itself. When the narrator reads the 2nd sentence, circle the "Severe pain" bar. Provide a link at the bottom of the page to a PDF of this scale.	**Narrator:** Paul describes his pain as dull, heavy, and exhausting. When his physician asks him to assess his level of pain using the Simple Descriptive Pain Intensity Scale, he rates it as "severe".
103	Animation of the CAGE-AID being filled out. For all questions, check off "No". Provide a link at the bottom of the screen to a PDF of the CAGE-AID.	**Narrator:** Paul's physician thinks he would be a good candidate for opioid therapy, ~~as he has not been prescribed them before~~. She assesses his risk for opioid abuse with the CAGE-AID tool. Paul answers "No" to all of the questions, indicating a low ~~risk for opioid abuse~~.
104	On-screen text: **How would you treat Paul?** a. Try a new NSAID or other pharmacologic agent b. Combine opioid therapy with a nonpharmacologic treatment option c. Prescribe opioid therapy alone	**Narrator:** How would you proceed with treatment for Paul? • Try a new NSAID or other pharmacologic agent • Combine opioid therapy with a nonpharmacologic treatment option • Or, prescribe opioids alone

105	On-screen text: **Paul is prescribed the smallest dose of a long-acting opioid.**	**Narrator:** ~~In order to gauge Paul's reaction to opioid therapy, his~~ Paul's physician decides to prescribe ~~the smallest~~ dose of a long-acting opioid. While Paul is at low risk for abuse, she makes sure to inform him about the potential risks with this type of agent and tells him that she will be conducting pill counts at his follow-up visits. Because Paul has 2 young children at home, she gives him information about proper pill storage and disposal.
106	On-screen text: At follow-up 1 month later • Pain intensity level now moderate • Can now sit at desk for up to 2 hours at a time • Bowel movements are regular • No interference with activities of daily living • Correct pill count	**Narrator:** On Paul's follow up examination 1 month later, he says that his pain intensity level is now moderate, and he can now sit at his desk for up to 2 hours at a time. His bowel movements are regular, and he has no interference with his activities of daily living. His pill counts are correct.
107	On-screen text: What would your next step be? a. Maintain current regimen b. Titrate his opioid dose upwards	**Narrator:** Given this information, what would your next step be? • Maintain Paul's current treatment regimen as is • Or, titrate his opioid dose upwards
108	On-screen text: Possible options for next steps • Maintain current regimen	**Narrator:** Since Paul seems to be improving, his physician may choose to maintain his current treatment regimen
109	On-screen text: Possible options for next steps • Titrate his opioid dose upwards	**Narrator:** On the other hand, she may feel that because Paul is responding so well to therapy, with very few side effects, his dose can be adjusted upwards to provide further pain relief. Whichever option she decides, she will need to continue to

		monitor Paul's progress to determine how long he will need to stay on long-acting opioids.

Moderate-Risk Patient 1: Kelly

Cell	Visual	Audio
101	On-screen text: Case Study: Kelly • 28 years old • 3-year history of polyarticular arthritis and joint pain • Pain is most severe in hands and feet • Pain increases late in the day and with activity	**Narrator:** Kelly is a 28-year-old woman who is new to the area and referred to the primary care practice. She has a 3-year history of polyarticular arthritis and joint pain. Kelly's pain is most severe in her hands and feet. There is a constant component, which increases late in the day and with activity.
102	On-screen text: Past Treatments • Was taking 2 TNF blockers, but stopped due to high readings on liver function tests • NSAID provides minimal pain relief • Former rheumatologist prescribed an opioid • Has been on a stable regimen of short- and long-acting opioids for about 1 year	**Narrator:** Kelly had been taking two different TNF blockers, but these were stopped due to high readings on her liver function tests. She is currently taking an NSAID, with minimal effect on the pain. Her former rheumatologist also prescribed an opioid along with the NSAID, and she has been on a stable regimen of both short- and long-acting opioids for about a year. She states that the opioids have "allowed her to live her life."
103	On-screen text: History • Concern that she will be unable to work due to pain • Limited social life • Sleeps poorly • Intermittent bouts of depression • Recovering methamphetamine user; has been attending Narcotics Anonymous meetings for 3 years • Denies current or past illegal alcohol abuse • No family history of alcohol or drug abuse	**Narrator:** Kelly is currently looking for work as a waitress; she is concerned that her pain will prevent her from working unless her current therapy is continued. She has a limited social life due to her pain and sleeps poorly, and reports intermittent bouts of depression. She is a recovering methamphetamine user and has been attending Narcotics Anonymous meetings for the last 3 years; she maintains that she has ~~been clean~~ during that entire time period. She denies any other current or past illegal alcohol abuse, and there is no family history of alcohol or drug abuse.

not used illicit drugs

104	Animation of the first page of the Brief Pain Inventory being filled out. Zoom in on Question 5, and show a large circle being drawn around the range of the numbers 3-8. Do the same for Question 6. Provide a link at the bottom of the page to a PDF of the BPI.	**Narrator:** After taking Kelly's history, her physician administers the Brief Pain Inventory. On a pain scale of 0 to 10, with 10 being the most severe, Kelly rates her overall pain as ranging from 3 to 8.
105	Animation of Patient Version of the Opioid Risk Tool (ORT) being filled out. As the narrator reads what her risk factors are, an animated pencil checks off the boxes marked "Personal History of Substance Abuse—Illegal Drugs", "Age", and "Psychological Disease—Depression". Provide a link at the bottom of screen to a PDF of the Patient ORT.	**Narrator:** Kelly is given the Opioid Risk Tool to fill out in order to assess her potential risk of abuse. She checks off the boxes about personal history of illegal drug abuse and history of depression.
106	View switches to the Physician Version of the ORT. The same boxes that were checked off on in the last scene are already filled out here. As the narrator talks, the scores for each category, under the "Item score if female" column, are somehow highlighted (maybe isolated and enlarged). The "Moderate risk" line under "Total score risk category" should be highlighted as well. Provide a link at the bottom of the screen to a PDF of the Physician ORT.	**Narrator**: Kelly's age, past history of illegal drug abuse, and history of depression give her a score of 6, indicating a moderate risk for opioid abuse.
107	On-screen text: How would you treat Kelly? a. Maintain both of her therapies b. Have her stop taking the NSAID but continue with both opioids c. Have her stop taking the NSAID but continue with just the long-acting opioid d. Adjust her opioid dosages e. Discontinue both opioids and prescribe a different NSAID or a new pharmacologic agent	**Narrator:** How would you proceed with treatment for Kelly? • Maintain both of her therapies • Have her stop taking the NSAID but continue with both opioids • Have her stop taking the NSAID but continue with just the long-acting opioid • Adjust her opioid dosages • Or, discontinue both opioids and prescribe a different NSAID or a new pharmacologic agent
108	On-screen text: **Kelly is maintained on opioids, but titrated**	**Narrator:** ~~While Kelly is looking for a renewal of her current opioid prescription~~, Kelly's physician

	down.	decided ~~that because of her risk factors and mental health, she should be titrated down to a low enough level that would~~ both ease her pain and to prevent withdrawal.
109	Show the first page of the Sample Controlled Substances Therapy Agreement. Provide a link at bottom of screen to a PDF of this document.	**Narrator:** To verify Kelly's history, a urine drug screen was given at this visit, and her physician will contact her former PCP, rheumatologist, and pharmacist. He also goes over an opioid therapy agreement with her and has her sign it, and discusses pill counting with her. Kelly will need to bring her pill bottle to her follow-up appointment in 1 week.
110	On-screen text: • Physician's office contacted previous pharmacist and health care providers, who confirmed history	**Narrator:** In the interim, Kelly's former PCP, rheumatologist, and pharmacist all confirmed her history.
111	On-screen text: **At follow-up 1 week later** • No pain relief; reported feeling "terrible" on smaller dose • Urine test negative • Pill count consistent	**Narrator:** At the follow-up visit 1 week later, Kelly reports that the past week, when she was taking the smaller opioid dose, had been "terrible" and requests a return to her previous dose. Her urine test results are negative and her pill count is consistent with the prescribed treatment.
112	On-screen text: **What would your next step be?** a. Discontinue opioid therapy and prescribe a different agent b. Maintain current regimen as is c. Return her to her previous opioid treatment regimen	**Narrator:** Given this information, what would your next step be? • Discontinue Ann's opioid therapy and prescribe a different agent • Maintain her current treatment regimen as is • Or, return her to her previous opioid regimen
113	On-screen text: **Possible options for next steps**	**Narrator:** Because Kelly's pain has returned and she has shown no signs of abuse or falsifying information, she will be returned to her previous

	• Return her to her previous treatment regimen • Remind her that she is not to get opioids from other clinicians or to use more than one pharmacy • Have her follow up with a new rheumatologist • Inform her that urine screenings will keep being performed and that she should bring pill bottles to all follow-up visits • Possible referral to a mental health professional	dose. She is told about the need for adherence with instructions to not get opioid prescriptions from other clinicians, to use only one pharmacy to fill her prescriptions, and to follow up with a new rheumatologist. She is also informed that urine drug screenings will be repeated ~~monthly~~ periodically and that she should continue to bring pill bottles to follow-up appointments. Kelly's physician also may wish to refer her to a mental health professional for treatment of her depression.

Moderate-Risk Patient 2: Jim

Cell	Visual	Audio
101	On-screen text: Case Study: Jim • 44 years old • Recurrent back pain since early 20s • Recently aggravated pain after tripping while getting out of his truck • Taking maximum doses of 2 NSAIDs with minimal relief • Gets best relief from lying on his side with a pillow between his legs	**Narrator:** Jim is a 44-year-old heavy machine operator who has had recurrent back pain since his early 20s. He recently tripped while descending from the cab of his truck, resulting in intense, sharp pain in his lower back. He has only gotten minimal relief with maximum doses of two different NSAIDs; his greatest pain relief comes from lying down on his side with a pillow between his legs. MRI did not show any identifiable change from prior studies
102	Medium shot of the Simple Descriptive Pain Intensity Scale tool, then close up on the scale itself. Circle the "Very severe pain" bar. Provide a link at the bottom of the page to a PDF of this scale.	**Narrator:** On the Simple Descriptive Pain Intensity Scale, Jim rates his pain as "very severe". He says that it feels like a continuous sharp ache in the lower back, radiating down into the right buttock, thigh, and right foot with certain movements.
103	On-screen text: • Has bouts of insomnia caused by pain disrupting sleep • Not depressed, but frustrated by lack of pain cessation • Former heavy alcohol user, but claims he quit drinking 2 years ago • Not in a recovery program	**Narrator:** Jim is currently experiencing bouts of insomnia caused by pain disrupting his sleep. He denies feeling depressed, but experiences frustration at not being able to experience any real pain cessation. His past history is noteworthy for heavy alcohol use; he is not in a recovery program, but he states that he discontinued all alcohol use when he began his current job 2 years ago.
105	Animation of Patient Version of the Opioid Risk Tool (ORT) being filled out. As the narrator reads what her risk factors are, an animated pencil checks off the boxes marked "Personal History of Substance Abuse—Alcohol", and "Age". Provide a link at the bottom of screen to a PDF of the Patient ORT.	**Narrator:** Given Jim's past history, his physician uses the Opioid Risk Tool to ~~check~~ document for the risk of potential opioid abuse.

106	View switches to the Physician Version of the ORT. The same boxes that were checked off on in the last scene are already filled out here. As the narrator talks, the scores for each category, under the "Item score if male" column, are somehow highlighted (maybe isolated and enlarged). The "Moderate risk" line under "Total score risk category" should be highlighted as well. Provide a link at the bottom of the screen to a PDF of the Physician ORT.	**Narrator**: Jim's score totals 4, indicating a moderate risk for opioid abuse.
107	On-screen text: How would you treat Jim? a. Prescribe an immediate-release opioid b. Prescribe a modified-release or long-acting opioid c. Advise that Jim seek nonpharmacologic treatment d. Recommend a combination of an opioid and nonpharmacologic treatment	**Narrator:** How would you proceed with treatment for Jim? • Prescribe an immediate-release opioid • Prescribe a modified-release or long-acting opioid • Advise that Jim seek nonpharmacologic treatment, such as physical therapy • Or, recommend a combination of an opioid and nonpharmacologic treatment
108	On-screen text: Jim is prescribed an **immediate-release opioid** and **is also advised to begin nonpharmacologic treatment**	**Narrator:** Jim's physician decides to prescribe an immediate-release opioid for his pain, as well as a prophylactic laxative. He is advised to begin nonpharmacologic courses of pain relief, including physical therapy.
109	On-screen text: Follow-up **1 month** later • Jim had missed 2 previously scheduled appointments • Has called office to ask for extra medication	**Narrator:** Jim comes in for a follow-up visit 1 month later. He had missed 2 previously scheduled appointments, claiming illness on one occasion and having to work overtime on the other. Though Jim's initial prescription was for a 2-month supply with no renewals, he has called his physician's office on a few occasions, asking for extra medication.
110	Animation of the Pain Assessment and Documentation Tool (PADT) being filled out.	**Narrator:** Jim's physician interviews him with the Pain Assessment and

believes that this episode is likely to be self-limited. For this reason, he

	When the narrator reads the 1st sentence, focus on the Analgesia section, circling "3" for Question 1, "4" for Question 2, writing in "70%" for Question 3, and checking off the "Yes" box for Question 4. When the narrator reads the 2nd sentence, focus on the Adverse Events section on the 2nd page and check "Yes" for Question 1, and "No" for all of the side effect boxes except for drowsiness, which is mild. Provide a link at bottom of screen to a PDF of the PADT.	Documentation Tool, or PADT. Jim tells his physician that his pain is much better, though sometimes it worsens when he engages in activities at work that strain his back. He says that during those times, he takes additional doses of his opioids to relieve the pain. He has been experiencing some mild drowsiness, but the laxative is helping to keep constipation under control. Jim has been going to physical therapy sessions twice a week, and thinks they have helped him a little.
111	Stay on the 2nd page of the PADT. Focus on the Potential Aberrant Drug-Related Behavior section on the 2nd page, and check off the "Requests frequent early renewals" and "Increased dose without authorization" boxes. Write in under "Other", this text: **Has cancelled 2 separate follow-up visits.**	**Narrator:** Jim's physician makes note of his requests for medication renewals, additional medication use, and follow-up visit cancellations.
112	On-screen text: What would your next step be? a. Maintain current regimen as is, but monitor his activities b. Discontinue opioid therapy and prescribe a different agent c. Switch him to a long-acting opioid	**Narrator:** Given this information, what would your next step be? • Maintain his current regimen as it, but monitor his activities • Discontinue Jim's opioid therapy and prescribe a different agent • Switch him to a long-acting opioid
113	On-screen text: **Possible options for next steps** • Maintain current regimen as is, but monitor his activities • Remind him that he is not to escalate his dose without physician approval or call the office for medication requests • Jim's physician will train his staff on how to handle patient requests for controlled substances	**Narrator:** Jim's physician feels that ~~the opioids~~ are helping him, but he is concerned that Jim may be stockpiling ~~pills or relying on them too heavily. Jim is reminded that his is not to escalate his dose without his physician's approval, and that he is~~ not to call the office to ask for extra medication. Jim's physician will also train his staff about the internal policy governing requests by patients for opioids and other controlled

about Jim's drug-taking behavior
Jim is counseled about the need for adherence to all instructions. He is

		substances, and let them know that they are defer those calls directly to him.
114	On-screen text: Possible options for next steps • Screen urine now, and possibly at future follow-up visits • Ask for an "excuse note" for follow-up appointment cancellations • Have Jim purchase a topical anesthetic cream to help with pain at work • Provide handouts on relaxation techniques and proper methods for lifting and bending	**Narrator:** At this visit, Jim's physician will administer a urine screening test; the results will determine whether he will use this test on follow-up visit. Jim is asked to keep all follow-up appointments, and to provide a note from his employer should he have to cancel. ~~He is also asked to purchase an over-the-counter topical anesthetic cream to help with his pain at work and~~ is given handouts on relaxation techniques and how to properly lift and bend.

High-Risk Patient 1: Ann

Cell	Visual	Audio
101	On-screen text: Case Study: Ann • 50 years old • 5-year history of severe OA in her hands • Describes pain as sharp, knifelike, relentless, and unbearable • Rates pain as 10 (worst) on the Pain Numeric Rating Scale (NRS) • No relief from medications	**Narrator:** Ann is a 50-year-old woman with a 5-year history of severe osteoarthritis in her hands, which has severely affected her ability to fulfill her typing duties as an executive assistant. She describes her pain as sharp, knifelike, relentless, and unbearable, and rates her pain as a 10 on the Pain Numeric Rating Scale, or NRS. No previous medications have given her relief.
102	On-screen text: History • Past medical history of anxiety • Past marijuana and cocaine use • Clean for 2 years; occasionally attends CA meetings but no formal substance abuse treatment • Does not see a mental health professional • Father has history of alcoholism and prescription drug abuse	**Narrator:** Ann has a past medical history of anxiety as well as marijuana and cocaine use, though she has been clean for 2 years. She occasionally attends Cocaine Anonymous meetings, but has not undergone formal substance abuse treatment and does not see a mental health professional. Her family history is positive for alcoholism and prescription drug abuse in her father.
103	Animation of Patient Version of the Opioid Risk Tool (ORT) being filled out. As the narrator reads what her risk factors are, an animated pencil checks off the boxes marked "Family History of Substance Abuse-Alcohol", "Family History of Substance Abuse—Prescription Drugs", and "Personal History of Substance Abuse—Illegal Drugs". Provide a link at the bottom of screen to a PDF of the Patient ORT.	**Narrator:** Ann is given the Opioid Risk Tool to fill out in order to assess her potential risk of abuse. She checks off the boxes about family history and personal history of substance abuse.
104	View switches to the Physician Version of the ORT. The same boxes that were checked off on in the last scene are already filled out here. As the narrator talks, the scores for each category, under the "Item score if female" column, are somehow highlighted (maybe isolated and enlarged). The "High risk" line under "Total score risk category" should be highlighted as well.	**Narrator**: Ann's personal and family history give her a score of 9, indicating a high risk for opioid abuse.

	Provide a link at the bottom of the screen to a PDF of the Physician ORT.	
105	On-screen text: **How would you treat Ann?** a. Proceed with opioid therapy b. Try a new NSAID or other pharmacologic agent c. Suggest a nonpharmacologic option (eg, physical therapy) d. A combination of one or more of these options, along with substance abuse treatment	**Narrator:** How would you proceed with treatment for Ann? • Proceed with opioid therapy • Try a new NSAID or other pharmacologic agent • Suggest a nonpharmacologic option, such as physical therapy • Or, a combination of one or more of these options, along with substance abuse treatment
106	On-screen text: **Ann is started on opioid therapy, with the guidance of an addiction medicine specialist.**	**Narrator:** Ann's physician feels that she merits a trial of opioid therapy, given her painful disease, difficulty obtaining relief with other agents, and strong interest in maintaining her job. Her treatment plan consists of trialing a long-acting opioid in concert with the guidance of an addiction medicine specialist. Ann's treatment will be co-managed with the addiction medicine specialist in order to reduce the risk of opioid misuse or abuse.
107	Show the first page of the Sample Controlled Substances Therapy Agreement. Provide a link at bottom of screen to a PDF of this document.	**Narrator:** Ann's physician obtains a urine sample from her. He also goes over an opioid therapy agreement with her and has her sign it, ~~and mentions the importance of pill counting.~~
108	On-screen text: **Ann is given a 2-week supply of opioids and will be followed up**	**Narrator:** Ann is given a 2-week supply of opioids, which will require a follow-up visit. This will enable her physician to more closely monitor the patient for opioid misuse or use of illicit substances.
109	On-screen text: **At follow-up 2 weeks later**	**Narrator:** The follow-up visit 2 weeks later finds Ann with 50% pain relief, an increased ability to type, and an

reducing her pain

	• 50% pain relief • Increased ability to type • Improved mood • Urine test negative, but 5 pills missing from pill count	improved mood. While urine testing from the first visit is negative, 5 pills are missing from the pill count. Ann says that she needed to take "extra" pills to cover 2 days of extreme pain.
110	On-screen text: What would your next step be? a. Discontinue opioid therapy and prescribe a different agent b. Maintain current regimen as is c. Keep her on opioids, but remind her of the parameters of the treatment agreement and keep a close watch on her activities	**Narrator:** Given this information, what would your next step be? • Discontinue Ann's opioid therapy and prescribe a different agent • Maintain her current treatment regimen as is • Or, keep her on opioids, but reminder her of the parameters of the treatment agreement and keep a close watch on her activities
111	On-screen text: Possible options for next steps • Reiterate that opioid treatment agreement states that there are to be no dose escalations without physician consent	**Narrator:** Ann's opioid therapy seems to be ~~going well~~, and the discrepancy in the pill count is the only red flag. However, because she is at high risk for abuse, her physician may want to reiterate the part of the opioid treatment agreement that says that no unsanctioned dose escalations should occur without contacting him.
111	On-screen text: Possible options for next steps • Prescribe another 2-week course of opioid therapy, but obtain a urine sample • Let her know how many "infractions" will be allowed before opioid therapy is stopped • Consult with addiction medicine specialist to monitor Ann's progress	**Narrator:** At this stage, Ann could receive another prescription for 2 weeks of opioid therapy. But, she will have to give another urine sample, and her physician will need to inform her how many so-called "infractions" he will allow before stopping her opioid therapy. Her physician should also consult with the addiction management specialist to monitor Ann's progress.

High-Risk Patient 1: Ann

Cell	Visual	Audio
101	On-screen text: Case Study: Ann • 50 years old • 5-year history of severe OA in her hands • Describes pain as sharp, knifelike, relentless, and unbearable • Rates pain as 10 (worst) on the Pain Numeric Rating Scale (NRS) • No relief from medications	**Narrator:** Ann is a 50-year-old woman with a 5-year history of severe osteoarthritis in her hands, which has severely affected her ability to fulfill her typing duties as an executive assistant. She describes her pain as sharp, knifelike, relentless, and unbearable, and rates her pain as a 10 on the Pain Numeric Rating Scale, or NRS. No previous medications have given her relief.
102	On-screen text: History • Past medical history of anxiety • Past marijuana and cocaine use • Clean for 2 years; occasionally attends CA meetings but no formal substance abuse treatment • Does not see a mental health professional • Father has history of alcoholism and prescription drug abuse	**Narrator:** Ann has a past medical history of anxiety as well as marijuana and cocaine use, though she has been ~~clean~~ for 2 years. She occasionally attends Cocaine Anonymous meetings, but has not undergone formal substance abuse treatment and does not see a mental health professional. Her family history is positive for alcoholism and prescription drug abuse in her father.
103	Animation of Patient Version of the Opioid Risk Tool (ORT) being filled out. As the narrator reads what her risk factors are, an animated pencil checks off the boxes marked "Family History of Substance Abuse-Alcohol", "Family History of Substance Abuse—Prescription Drugs", and "Personal History of Substance Abuse—Illegal Drugs". Provide a link at the bottom of screen to a PDF of the Patient ORT.	**Narrator:** Ann is given the Opioid Risk Tool to fill out in order to assess her potential risk of abuse. She checks off the boxes about family history and personal history of substance abuse.
104	View switches to the Physician Version of the ORT. The same boxes that were checked off on in the last scene are already filled out here. As the narrator talks, the scores for each category, under the "Item score if female" column, are somehow highlighted (maybe isolated and enlarged). The "High risk" line under "Total score risk category" should be highlighted as well.	**Narrator**: Ann's personal and family history give her a score of 9, indicating a high risk for opioid abuse.

	Provide a link at the bottom of the screen to a PDF of the Physician ORT.	
105	On-screen text: **How would you treat Ann?** a. Proceed with opioid therapy b. Try a new NSAID or other pharmacologic agent c. Suggest a nonpharmacologic option (eg, physical therapy) d. A combination of one or more of these options, along with substance abuse treatment	**Narrator:** How would you proceed with treatment for Ann? • Proceed with opioid therapy • Try a new NSAID or other pharmacologic agent • Suggest a nonpharmacologic option, such as physical therapy • Or, a combination of one or more of these options, along with substance abuse treatment
106	On-screen text: **Ann is started on opioid therapy, with the guidance of an addiction medicine specialist.**	**Narrator:** Ann's physician feels that she merits a trial of opioid therapy, given her painful disease, difficulty obtaining relief with other agents, and strong interest in maintaining her job. Her treatment plan consists of trialing a long-acting opioid in concert with the guidance of an addiction medicine specialist. Ann's treatment will be co-managed with the addiction medicine specialist in order to reduce the risk of opioid misuse or abuse.
107	Show the first page of the Sample Controlled Substances Therapy Agreement. Provide a link at bottom of screen to a PDF of this document.	**Narrator:** Ann's physician obtains a urine sample from her. He also goes over an opioid therapy agreement with her and has her sign it, ~~and mentions the importance of pill counting.~~
108	On-screen text: **Ann is given a 2-week supply of opioids and will be followed up**	**Narrator:** Ann is given a 2-week supply of opioids, which will require a follow-up visit. This will enable her physician to more closely monitor the patient for opioid misuse or use of illicit substances.
109	On-screen text: **At follow-up 2 weeks later**	**Narrator:** The follow-up visit 2 weeks later finds Ann with 50% pain relief, an increased ability to type, and an

reducing her pain

	• 50% pain relief • Increased ability to type • Improved mood • Urine test negative, but 5 pills missing from pill count	improved mood. While urine testing from the first visit is negative, 5 pills are missing from the pill count. Ann says that she needed to take "extra" pills to cover 2 days of extreme pain.
110	On-screen text: What would your next step be? a. Discontinue opioid therapy and prescribe a different agent b. Maintain current regimen as is c. Keep her on opioids, but remind her of the parameters of the treatment agreement and keep a close watch on her activities	**Narrator:** Given this information, what would your next step be? • Discontinue Ann's opioid therapy and prescribe a different agent • Maintain her current treatment regimen as is • Or, keep her on opioids, but reminder her of the parameters of the treatment agreement and keep a close watch on her activities
111	On-screen text: Possible options for next steps • Reiterate that opioid treatment agreement states that there are to be no dose escalations without physician consent	**Narrator:** Ann's opioid therapy seems to be ~~going well~~, and the discrepancy in the pill count is the only red flag. However, because she is at high risk for abuse, her physician may want to reiterate the part of the opioid treatment agreement that says that no unsanctioned dose escalations should occur without contacting him.
111	On-screen text: Possible options for next steps • Prescribe another 2-week course of opioid therapy, but obtain a urine sample • Let her know how many "infractions" will be allowed before opioid therapy is stopped • Consult with addiction medicine specialist to monitor Ann's progress	**Narrator:** At this stage, Ann could receive another prescription for 2 weeks of opioid therapy. But, she will have to give another urine sample, and her physician will need to inform her how many so-called "infractions" he will allow before stopping her opioid therapy. Her physician should also consult with the addiction management specialist to monitor Ann's progress.

High-Risk Patient 2: Ben

Cell	Visual	Audio
101	On-screen text: **Case Study: Ben** • 35 years old • Nonspecific chronic low back pain • Works as a bus driver, but has been out on disability for 9 months • Employer and insurance company have been asking about his work availability • Longstanding GERD • Overweight • Has not maintained a physical therapy regimen • Smokes 2 packs of cigarettes/week and consumes a 6-pack of beer daily • Reports feeling depressed	**Narrator:** Ben is a 35-year-old man with nonspecific chronic low back pain who is referred for evaluation and pain management. He is a bus driver who has been out on disability for 9 months, and he has been receiving inquiries from his employer and health insurance company regarding his availability for work. He has longstanding GERD and is overweight, and has not maintained a physical therapy regimen. He smokes 2 packs of cigarettes a week and consumes a 6-pack of beer daily. He reports feeling depressed due to his pain and the pressure on him to return to work.
102	Animation of the first page of the Brief Pain Inventory being filled out. Zoom in on Question 5, and show a circle being drawn around the number 8. Provide a link at the bottom of the screen to a PDF of the BPI.	**Narrator:** Using the Brief Pain Inventory, on a pain scale of 0 to 10, with 10 being the most severe, Ben rates his overall pain as 8.
103	Animation of the CAGE-AID being filled out. For Questions 1 & 3, check off "No", and for Questions 2 & 4, check off "Yes". Provide a link at the bottom of the screen to a PDF of the CAGE-AID.	**Narrator**: Ben's physician decides to assess his potential for opioid abuse by first administering the CAGE-AID tool. Ben answers "Yes" to 2 of the questions, indicating that a more detailed assessment will need to be done with a more specific tool.
104	Animation of Patient Version of the Opioid Risk Tool (ORT) being filled out. As the narrator reads the 2nd sentence, an animated pencil checks off the boxes marked "Family History of Substance Abuse—Alcohol", "Personal History of Substance Abuse—Alcohol", "Age", and "Psychological Disease—Depression". Provide a link at the bottom of the screen to a PDF of the Patient ORT.	**Narrator:** Ben is then given the Opioid Risk Tool to fill out. He checks off the boxes about a personal history of alcohol abuse and depression and a family history of alcoholism.
105	View switches to the Physician Version of the ORT. The same boxes that were checked off on in	**Narrator**: Ben's personal and family history, plus his age, give him a score

NB: I would not agree. He may be actual alcoholic — not appropriate for opioid treatment right now

	the last scene are already filled out here. As the narrator talks, the scores for each category, under the "Item score if male" column, are somehow highlighted (maybe isolated and enlarged). The "High risk" line under "Total score risk category" should be highlighted as well. Provide a link at the bottom of the screen to a PDF of the Physician ORT.	of 8, indicating a high risk for opioid abuse.
106	On-screen text: **How would you treat Ben?** a. Proceed with opioid therapy b. Try a new NSAID or other pharmacologic agent c. Suggest a nonpharmacologic option (eg, physical therapy) d. A combination of one or more of these options	**Narrator:** How would you proceed with treatment for Ben? • Proceed with opioid therapy • Try a new NSAID or other pharmacologic agent • Suggest a nonpharmacologic option, such as physical therapy • Or, a combination of one or more of these options
107	On-screen text: Ben is started on low-dose opioid and prescribed weekly at-home physical therapy sessions. It is recommended that he see a mental health professional for his depression.	**Narrator:** Because of the severity of his pain, Ben is prescribed a low-dose opioid and weekly at-home physical therapy sessions, and is asked to refrain from drinking. His physician gives him a referral for a mental health professional to treat his depression.
108	Show the first page of the Sample Controlled Substances Therapy Agreement. Provide a link at bottom of the screen to a PDF of this document.	**Narrator:** Ben is given a urine drug test, and he and his physician work out a long-term plan that will provide structure, support, and monitoring for pain management with the opioid.
109	On-screen text: **At follow-up 3 weeks later** • Ben claims he lost pills 5 days ago and needs more • Has been shopping around to get an additional prescription for opioids because of his pain • Physical therapy sessions cancelled twice	**Narrator:** At the follow-up visit 3 weeks later, Ben claims that he lost his pills 5 days ago and needs a new prescription. The practice has learned that he has also shopped around for another physician to obtain an additional prescription for opioids because his pain has been intense. Twice, he cancelled his physical therapy

	due to "illness" • Urine test positive • Opioid abuse suspected	sessions due to an unspecified "illness", and his urine test results are positive. All of these factors raise red flags for Ben's physician, who now suspects opioid abuse.
110	Animation of the Pain Assessment and Documentation Tool (PADT) being filled out. When the narrator reads the 2nd sentence, focus on the Analgesia section, circling "6" for Questions 1 and 2, writing in "40%" for Question 3, and checking off the "No" box for Question 4. When the narrator reads the 3rd sentence, focus on the Activities of Daily Living section and check the "Same" box for each question. When the narrator reads the 4th sentence, focus on the Potential Aberrant Drug-Related Behavior section on the 2nd page, and check off the "Reports lost or stolen prescription" and "Attempts to obtain other prescriptions…" boxes. Write in under "Other", this text: **Has cancelled physical therapy sessions for unspecified reasons.** Provide a link at bottom of screen to a PDF of the PADT.	Ben's physician interviews him further, using the Pain Assessment and Documentation Tool, or PADT. He notes that Ben claims only limited relief with his current opioid therapy. Ben also seems to show no improvement in his activities of daily living. He admitted to 2 of the potential aberrant drug-related behaviors, and his physician makes note of his physical therapy session cancellations.
111	On-screen text: **What would your next step be?** a. Maintain current regimen b. Discontinue opioid therapy and prescribe a different agent c. Keep him on opioids, but administer urine drug screens and interview him at every follow-up session, and keep a close watch on his activities	**Narrator:** Given this information, what would your next step be? • Maintain Ben's current treatment regimen as is • Discontinue opioid therapy and prescribe a different agent • Or, keep him on opioids, but administer a urine toxicology test and interview him at every follow-up session, and keep a close watch on his activities

112	On-screen text: **Possible options for next steps** • Discontinue opioid therapy and prescribe a different agent	**Narrator:** Ben's physician may decide that because of the red flags, and the fact that opioids may or may not be helping his pain, it would be best to try another agent with less potential for risk.
113	On-screen text: **Possible options for next steps** • Keep him on opioids and/or change his dose, but administer a urine toxicology test and interview him at every follow-up session • Follow-up sessions every 2 weeks • Double-check prescription filling with area pharmacies and health care professionals • May need to stop opioid therapy and refer Ben to an addiction management program if signs of abuse continue	**Narrator:** If Ben's physician decides to maintain his current opioid regimen, Ben would need to have his urine checked and sit for an interview at every follow-up session, which would occur weekly. His physician would monitor his activities to make sure that he is complying with both his medication and physical therapy regimens, and double-check with area pharmacies and health care providers to make sure that Ben is not trying to get extra opioids. If evidence of opioid abuse persists, his physician will then need to decide whether or not to stop opioid therapy, and also if he should refer Ben to an addiction management program.

NB:
This case needs major revision
Diagnose Alcoholism first.
Initiate addiction treatment.
If patient is able to engage for a while, opioid might be considered.
This is the type of patient that most PCP's should not treat.

REMS: Risk Evaluation and Mitigation Strategies

Through the Food and Drug Administration Amendments Act of 2007, the FDA has the authority to require a Risk Evaluation and Mitigation Strategy (REMS) from manufacturers to make certain that the benefits of a drug or biological product outweigh its risks. The FDA may require manufacturers to submit a REMS with products that have known or potential safety risks.

Each REMS must contain a timetable for assessment and can consist of one or more of the following components:

1. Medication guide for educating patients
2. Communication plan explaining the REMS requirements to healthcare providers
3. Elements to assure safe use: to mitigate serious risks through training, certification of HCPs and pharmacists, restrictions on dispensing, evidence of patient safe-use conditions, patient monitoring, and/or enrollment of patients into a registry
4. Implementation system: to monitor, evaluate, and improve elements to assure safe use

The REMS requirement is being applied to opioids, but are not intended solely for them. A list of opioids that may need to have a REMS can be found at the FDA's Opioid Products Chart.

When a new opioid REMS is approved, you may not be able to prescribe or dispense that opioid until you meet the REMS requirements. You can prepare now by educating your staff on REMS standard operating procedures; talking to your patients about the REMS requirements, the risks of opioids and how REMS is designed to minimize those risks, and safe storage and disposal of opioids; and familiarizing yourself with REMS and federal and state regulations. Information about federal regulations can be found at the Federation of State Medical Boards Web site; click this link for state regulations.

must

abusable drugs

assessment including the use of approaches

Documentation and Monitoring

Because opioids are potentially ~~addictive~~, patients should be monitored during their entire course of therapy. During patient visits, health care professionals need to look for indications of possible abuse. This can be accomplished through ~~both~~ clinical ~~decision making and certain screening tools~~, such as urine toxicology screens and medication counts. Informed consent agreements let patients know how the drug will be prescribed and what is expected of them. Because clinic staff are on the "front lines," educating them on signs of abuse and installing screening processes can help protect your practice from liability.

some

[clickable button for Staff Education page]
[clickable button for Patient Informed Consent page]
[clickable button for Urine Toxicology Screen and Medication Counts page]

specialists to believe that they should be used routinely others do not.

This applies to all patients and can be likened to a "Universal Precautions" approach.

Documentation and Monitoring
Staff Education

During their visits, patients will spend a good deal of time interacting with clinic staff, including receptionists, nurses, and physician assistants. Therefore, staff can help screen patients for possible signs of substance abuse.

[video]

Patients who are taking opioids are often stigmatized as potential abusers, no matter what their level of risk. It is important to educate staff on the benefits of long-term opioid therapy for pain reduction and the need to treat all patients respectfully, so that they do not inadvertently give negative commentary to patients.

Script

Documentation and Monitoring

Staff Education

Cell	Visual	Audio
101	KTL onscreen.	**Narrator:** During their visits, patients will spend a good deal of time interacting with clinic staff, including receptionists, nurses, and physician assistants. Therefore, it is important to educate staff on how to detect possible signs of substance abuse in patients taking opioids.
102	KTL onscreen.	**Narrator:** For example, receptionists and office managers could be instructed to inform patients who request prescriptions for opioids over the phone that they must come into the office for a full visit in order to receive a prescription.
103	KTL onscreen.	**Narrator:** Patients who are taking opioids are often stigmatized as potential abusers, no matter what their level of risk.
104	Onscreen text: **Make your staff aware about the benefits of long-term opioid therapy for pain reduction and the need to treat all patients respectfully**	**Narrator:** Make your staff aware about the benefits of long-term opioid therapy for pain reduction and the need to treat all patients respectfully, so that they do not inadvertently give negative commentary to patients.

Documentation and Monitoring
Patient Informed Consent

While informed consent agreements are not mandatory when prescribing a course of opioid therapy, they can be helpful for both the patient and the health care professional. These agreements may be verbal or written, simple or complex.

[video]

If you decide to give your patients a consent agreement, you can choose to have a standard version for everyone or one that is customized for each patient. The American Academy of Pain Medicine has devised a sample Long-Term Controlled Substances Therapy for Chronic Pain Agreement; click here [link to Sample Controlled Substances Therapy Agreement] to download a copy.

Script
Documentation and Monitoring
Patient Informed Consent

Cell	Visual	Audio
101	KTL onscreen.	**Narrator:** While informed consent agreements are not mandatory when prescribing a course of opioid therapy, they can be helpful for both the patient and the health care professional. They help create boundaries and facilitate safe opioid use by defining patient-prescriber expectations and responsibilities, as well as clearly outlining the risks associated with opioids. These agreements may be verbal or written, simple or complex.
102	KTL onscreen.	**Narrator:** If you decide to give your patients a consent agreement, you can choose to have a standard version for everyone or one that is customized for each patient.
103	Opening medium shot of the Sample Controlled Substances Therapy Agreement, with a pan down during the narration.	**Narrator:** The American Academy of Pain Medicine has devised a sample Long-Term Controlled Substances Therapy for Chronic Pain Agreement. This can be used as is, or serve as a template for your own form.

Documentation and Monitoring
Urine Toxicology Screens and Medication Counts

Urine toxicology screens and medication counts have been frequently used to monitor patients of all risk types. ~~Since all patients are unique, critical decision-making is often a more reliable form of risk assessment. However, these instruments~~ are often employed as part of a "Universal Precautions" ~~addiction~~ assessment strategy, as outlined by Douglas Gourlay and ~~colleagues~~ in 2005.

Your state's guidelines may require that you conduct regular patient screenings, using a urine toxicology screen and/or a medication count. A directory of state medical and osteopathic boards can be found at the Federation of State Medical Boards Website: http://www.fsmb.org/directory_smb.html.

Universal Precautions in Pain Medicine[1]

1. Make a diagnosis with appropriate differential
2. Perform a psychological assessment, including risk of addictive disorders
3. Informed consent: discuss proposed treatment plan with patient, including benefits and risks of therapy
4. Develop a treatment agreement
5. Conduct both pre- and post-intervention assessments of pain level and function
6. Prescribe an appropriate trial of opioid therapy, with or without adjunctive medication
7. Reassess pain score and level of function
8. Regularly assess the "4 As" of pain medicine: analgesia, activity, adverse effects, and aberrant behavior
9. Periodically review pain diagnosis and comorbid conditions, including addictive disorders
10. Documentation: record initial evaluation and each follow-up visit

Reference
1. Gourlay DL, Heit HA, Almahrezi A. Universal precautions in pain medicine: a rational approach to the treatment of chronic pain. *Pain Med*. 2005;6:107-112.

Patient Education

Patients are often unaware of the special precautions that need to be taken with opioids. Therefore, it is important that they and their families and caregivers be educated on the proper ways to store and dispose of their medications. They should also be given information on the potential adverse events associated with opioids, as well as the dangers of sharing drugs.

[clickable button for Drug Storage and Sharing page]
[clickable button for Drug Disposal and Destruction page]
[clickable button for Adverse Events page]

Patient Education
Drug Storage and Sharing

It's important that when patients are started on a course of opioid therapy, they are given information about proper drug storage and the hazards of sharing their medications.

The National Council on Patient Information and Education (NCPIE) recommends that patients store opioids in a locked cabinet or drawer. This not only prevents children from accessing them—a concern for all medications—but also discourages theft or misuse by strangers and family members. Patients should be told that opioids prescribed for them are for their use only, and it is illegal and dangerous for these agents to be given to anyone else, even people with similar conditions or kinds of pain.

A downloadable patient education sheet can be accessed on the NCPIE's Web site.

Patient Education
Drug Disposal and Destruction

Patients should be counseled about the importance of storing opioid analgesics safely and out of reach of children, other household members, visitors and pets, and protected from theft or misuse. Accidental consumption especially in children may result in overdose or death. When opioid analgesics are no longer needed, they should be disposed of in the manner described in the Full Prescribing Medication or in the linked documents below.

The Federal Guidelines for the Proper Disposal of Prescription Drugs can be accessed at the Web site of the Office of National Drug Control Policy. Click here for information from the Food and Drug Administration on which medicines can be safely disposed via flushing.

Although there is large patient-to-patient variation in the adverse effects experienced for a specific opioid the range of effects is common to all.

Patient Education
Adverse Events

~~Each opioid varies in its makeup and thus has specific indications, usage, and mechanisms of actions. However, patients should be informed of certain potential adverse events that are common to all opioids.~~

Overdose

Instruct patients against the use by individuals other than the patient for whom you have prescribed the opioid analgesic, as such inappropriate use may have severe medical consequences, including death. Persons who are not prescribed an opioid analgesic can overdose by taking even one dose. Persons who have a prescription for an opioid analgesic can overdose by taking more than the amount prescribed.

~~Certain doses of specific~~ opioid analgesics may cause fatal respiratory depression if taken by patients who have not developed tolerance to the respiratory depressant or sedating effects of opioids, or if taken at doses that overwhelm tolerance in the opioid-treated patient.
Manipulation by any means of any opioid analgesic dosage form poses a significant risk that could result in overdose and death. The risk of fatal outcome is increased with concurrent use or abuse of alcohol or other CNS depressants.

Respiratory Depression

Respiratory depression is the most significant serious adverse event risk with all opioid agonists, which can result in death.

The risk of respiratory depression is increased in elderly or debilitated patients, and in patients receiving ~~usually following large initial doses in persons who have not developed any degree of tolerance to the respiratory-depressant or sedating effects of opioid analgesics, or when opioids are given~~ in conjunction with other agents that depress respiratory drive or consciousness.

Addiction, Abuse, and Diversion

~~There is a potential for drug addiction to develop following exposure to opioids even under appropriate medical use.~~ All patients treated with opioids require careful monitoring for signs of abuse and addiction.

Opioid agonists have the potential to be abused and are subject to criminal diversion. Educate patients that sharing, giving, loaning, and selling one's opioid analgesics are dangerous and unlawful.

Physical Dependence and Tolerance should be assumed to occur

The development of physical dependence and/or tolerance ~~is not unusual~~ during chronic opioid therapy.

Also address non-adherence & frank abuse. Reassess, determine the cause, make a tentative diagnosis of addiction & appropriate Dec[illegible] the drug, continue and more controls

When a patient no longer requires therapy with an opioid, the daily dose should be tapered gradually to prevent signs and symptoms of withdrawal syndrome in the physically-dependent patient.

must be used very cautiously

Contraindications

Opioids ~~are contraindicated~~ in any setting with a risk of significant respiratory depression, in patients who have acute or severe bronchial asthma, in patients who have or are suspected of having paralytic ileus, or in patients ~~with known hypersensitivity to any of the opioid product's constituents~~ otherwise predisposed to opioid side effects

Serious Side Effects

Respiratory depression, apnea, respiratory arrest, and to a lesser degree, circulatory depression, hypotension, shock, or cardiac arrest have all been associated with opioid use and abuse.

Common Side Effects

mental clouding, drowsiness,

Nausea, vomiting, ~~dizziness, drowsiness~~, constipation, itching, dry mouth, sweating, ~~weakness, and headache~~ are the most common non-serious side effects of opioid analgesics.

Opioid analgesics may cause drowsiness, dizziness, or lightheadedness and may impair mental and/or physical ability required for the performance of potentially hazardous tasks (e.g. driving, operating machinery). Patients should be cautioned accordingly.

Additional Resources

The U.S. Department of Health and Human Services' Substance Abuse & Mental Health Services Administration has many useful online resources for health care professionals who have patients with substance abuse problems. For more information, visit their Web site using the links below:

- Substance Abuse Treatment Facility Locator
- State Substance Abuse Agencies

Russell Portenoy, MD

From: Leveene, Stephanie, Springer US [Stephanie.Leveene@springer.com]
Sent: Tuesday, January 18, 2011 11:37 AM
To: Russell Portenoy, MD
Subject: RE: Content for Purdue Opioid Resource CD-ROM: Text Files

Dear Dr. Portenoy,

Here are links to all of the pages. Please let me know if you have any questions.

Homepage: http://dl.dropbox.com/u/7223957/Homepage.docx

Section 1, Advisory Panel: http://dl.dropbox.com/u/7223957/Section%201.%20Advisory%20Panel.docx

Section 2, Recommendations: http://dl.dropbox.com/u/7223957/Section%202.%20Recommendations.docx

Section 3, Patient Evaluation Tools :
http://dl.dropbox.com/u/7223957/Section%203.%20Patient%20Evaluation%20Tools.docx

3A, Risk Assessment Tools:
http://dl.dropbox.com/u/7223957/Section%203A.%20Risk%20Assessment%20Tools.docx

3A-1, CAGE-AID Text Page: http://dl.dropbox.com/u/7223957/Section%203A-1.%20CAGE-AID.docx

3A-1, CAGE-AID Video Script: http://dl.dropbox.com/u/7223957/Section%203A-1%20Script.%20CAGE-AID.docx

3A-2, ORT Text Page: http://dl.dropbox.com/u/7223957/Section%203A-2.%20Opioid%20Risk%20Tool%20%28ORT%29.docx

3A-2, ORT Video Script: http://dl.dropbox.com/u/7223957/Section%203A-2%20Script.%20Opioid%20Resource%20Tool%20%28ORT%29.docx

3B, Patient Evaluation Tools:
http://dl.dropbox.com/u/7223957/Section%203B.%20Pain%20Inventory%20Tools.docx

3B-1, Brief Pain Inventory Text Page: http://dl.dropbox.com/u/7223957/Section%203B-1.%20Brief%20Pain%20Inventory.docx

3B-1, Brief Pain Inventory Video Script: http://dl.dropbox.com/u/7223957/Section%203B-1%20Script.%20Brief%20Pain%20Inventory.docx

3B-2, PADT Text Page: http://dl.dropbox.com/u/7223957/Section%203B-2.%20PADT.docx

3B-2, PADT Video Script: http://dl.dropbox.com/u/7223957/Section%203B-2%20Script.%20PADT.docx

3B-3, Simple Descriptive Pain Intensity Scale Text Page: http://dl.dropbox.com/u/7223957/Section%203B-3.%20Simple%20Descriptive%20Pain%20Intensity%20Scale.docx

3B-3, Simple Descriptive Pain Intensity Scale Video Script: http://dl.dropbox.com/u/7223957/Section%203B-3%20Script.%20Simple%20Descriptive%20Pain%20Intensity%20Scale.docx

Section 4, Case Vignettes: http://dl.dropbox.com/u/7223957/Section%204.%20Case%20Vignettes.docx

High-Risk Case 1: http://dl.dropbox.com/u/7223957/High-Risk%20Case%201--Script%20for%20Interactive%20Version.docx

High-Risk Case 2: http://dl.dropbox.com/u/7223957/High-Risk%20Case%202--Script%20for%20Interactive%20Version.docx

Moderate-Risk Case 1: http://dl.dropbox.com/u/7223957/Moderate-Risk%20Case%201--Script%20for%20Interactive%20Version.docx

Moderate-Risk Case 2: http://dl.dropbox.com/u/7223957/Moderate-Risk%20Case%202--Script%20for%20Interactive%20Version.docx

Low-Risk Case 1: http://dl.dropbox.com/u/7223957/Low-Risk%20Case%201--Script%20for%20Interactive%20Version.docx
Low-Risk Case 2: http://dl.dropbox.com/u/7223957/Low-Risk%20Case%202--Script%20for%20Interactive%20Version.docx

Section 5, REMS: http://dl.dropbox.com/u/7223957/Section%205.%20REMS.docx

Section 6, Documentation and Monitoring:
http://dl.dropbox.com/u/7223957/Section%206.%20Documentation%20and%20Monitoring.docx
6A, Staff Education Text Page: http://dl.dropbox.com/u/7223957/Section%206A.%20Staff%20Education.docx
6A, Staff Education Video Script:
http://dl.dropbox.com/u/7223957/Section%206A%20Script.%20Staff%20Education.docx
6B, Patient Informed Consent Text Page:
http://dl.dropbox.com/u/7223957/Section%206B.%20Patient%20Informed%20Consent.docx
6B, Patient Informed Consent Video Script:
http://dl.dropbox.com/u/7223957/Section%206B%20Script.%20Patient%20Informed%20Consent.docx
6C, Urine Toxicology Screen and Medication Counts:
http://dl.dropbox.com/u/7223957/Section%206C.%20Urine%20Toxicology%20Screen%20and%20Medication%20Counts.docx

Section 7, Patient Education: http://dl.dropbox.com/u/7223957/Section%207.%20Patient%20Education.docx
7A, Drug Storage and Sharing:
http://dl.dropbox.com/u/7223957/Section%207A.%20Drug%20Storage%20and%20Sharing.docx
7B, Drug Disposal and Destruction:
http://dl.dropbox.com/u/7223957/Section%207B.%20Drug%20Disposal%20and%20Distruction.docx
7C, Adverse Events: http://dl.dropbox.com/u/7223957/Section%207C.%20Adverse%20Events.docx

Section 8, Additional Resources: http://dl.dropbox.com/u/7223957/Section%208.%20Additional%20Resources.docx

---

From: Russell Portenoy, MD [mailto:RPorteno@chpnet.org]
Sent: Tuesday, January 18, 2011 10:50 AM
To: Leveene, Stephanie, Springer US
Cc: Adams, Kate, Springer Healthcare
Subject: RE: Content for Purdue Opioid Resource CD-ROM: Text Files

Thank you. The internet links would work I think.

From: Leveene, Stephanie, Springer US [mailto:Stephanie.Leveene@springer.com]
Sent: Tuesday, January 18, 2011 8:58 AM
To: Russell Portenoy, MD
Cc: Adams, Kate, Springer Healthcare
Subject: RE: Content for Purdue Opioid Resource CD-ROM: Text Files
Importance: High

Dear Dr. Portenoy,

I'm sorry you are having trouble with the zip file. I think it may be easier for me to print out everything and send them to you as hard copy, via Fed Ex. Alternately, I can copy them all into my Dropbox folder and send you an e-mail with individual Internet links to each file. Which would be best for you?

Sincerely,

Stephanie Leveene
Springer Healthcare LLC
Medical Writer

233 Spring Street | New York | NY 10013 | USA
tel: +1 212 460 1555
fax:+1 212 620 8442
mobile: +1 646 546 2361
E-mail: stephanie.leveene@springer.com

www.springerhealthcare.com

From: Russell Portenoy, MD [mailto:RPorteno@chpnet.org]
Sent: Tuesday, January 18, 2011 7:30 AM
To: Leveene, Stephanie, Springer US
Cc: Adams, Kate, Springer Healthcare
Subject: RE: Content for Purdue Opioid Resource CD-ROM--for your review

I am sorry but I am unable to open this zip file. There is an error message when I try to do so. Can you send it a different way?

From: Leveene, Stephanie, Springer US [mailto:Stephanie.Leveene@springer.com]
Sent: Tuesday, January 11, 2011 1:22 PM
To: Russell Portenoy, MD
Cc: Adams, Kate, Springer Healthcare
Subject: Content for Purdue Opioid Resource CD-ROM--for your review

Dear Dr. Portenoy,

I hope your new year has been going well so far. I'm writing to follow up on Kate Adams' note of December 16, 2010, regarding the next steps for the Purdue Opioid Resource project. Per her note, the draft content for the resource is attached for your review. This content can be broken down as follows:

- Plain text for the pages where there will be no interactivity
- Scripts for the several short videos that will explain how to use each featured tool and discuss staff education and patient informed consent. Once these scripts have been reviewed and updated, there will be a separate discussion as to which thought leader will narrate (and appear) on which video.
- Scripts for the interactive case studies. There are 6 cases: 2 each for low-, moderate-, and high-risk patients. We have designed these to be engaging to the user, with animated forms and questions about treatment (though the user will not be asked to pick an answer), and weaving in messages based on your 4 questions.

We would like to have your thoughts on these documents by **Monday, January 24**. Please don't hesitate to contact me or Kate Adams if you have any questions in the meantime. Purdue is very excited about this new, interactive format for the Opioid Resource, and we are looking forward to working with you on it in 2011.

Sincerely,

Stephanie Leveene
Springer Healthcare LLC
Medical Writer

233 Spring Street | New York | NY 10013 | USA
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mobile: +1 646 546 2361
E-mail: stephanie.leveene@springer.com

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Russell Portenoy, MD

From: Leveene, Stephanie, Springer US [Stephanie.Leveene@springer.com]
Sent: Tuesday, January 25, 2011 9:48 AM
To: Russell Portenoy, MD
Cc: Adams, Kate, Springer Healthcare
Subject: RE: Content for Purdue Opioid Resource CD-ROM--for your review

Dear Dr. Portenoy,

I'm writing to remind you that your comments on the Opioid Resource Content, as well as the wireframe that I sent last week, are now due. Could you please let me have your thoughts at your earliest convenience? Thank you very much.

Sincerely,

Stephanie Leveene
Springer Healthcare LLC
Medical Writer

233 Spring Street | New York | NY 10013 | USA
tel: +1 212 460 1555
fax:+1 212 620 8442
mobile: +1 646 546 2361
E-mail: stephanie.leveene@springer.com

www.springerhealthcare.com

From: Leveene, Stephanie, Springer US
Sent: Tuesday, January 11, 2011 1:22 PM
To: 'Russell Portenoy, MD'
Cc: Adams, Kate, Springer Healthcare
Subject: Content for Purdue Opioid Resource CD-ROM--for your review

Dear Dr. Portenoy,

I hope your new year has been going well so far. I'm writing to follow up on Kate Adams' note of December 16, 2010, regarding the next steps for the Purdue Opioid Resource project. Per her note, the draft content for the resource is attached for your review. This content can be broken down as follows:

- Plain text for the pages where there will be no interactivity
- Scripts for the several short videos that will explain how to use each featured tool and discuss staff education and patient informed consent. Once these scripts have been reviewed and updated, there will be a separate discussion as to which thought leader will narrate (and appear) on which video.
- Scripts for the interactive case studies. There are 6 cases: 2 each for low-, moderate-, and high-risk patients. We have designed these to be engaging to the user, with animated forms and questions about treatment (though the user will not be asked to pick an answer), and weaving in messages based on your 4 questions.

We would like to have your thoughts on these documents by **Monday, January 24**. Please don't hesitate to contact me or Kate Adams if you have any questions in the meantime. Purdue is very excited about this new, interactive format for the Opioid Resource, and we are looking forward to working with you on it in 2011.

Sincerely,

Stephanie Leveene
Springer Healthcare LLC
Medical Writer

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tel: +1 212 460 1555
fax:+1 212 620 8442
mobile: +1 646 546 2361
E-mail: stephanie.leveene@springer.com

www.springerhealthcare.com

Russell Portenoy, MD

From: Russell Portenoy, MD
Sent: Tuesday, January 25, 2011 3:55 PM
To: 'Leveene, Stephanie, Springer US'
Cc: Adams, Kate, Springer Healthcare
Subject: RE: Content for Purdue Opioid Resource CD-ROM: Text Files

Thanks very much. The wireframe is the overall interface? If so, then yes, and it seems fine to me.

From: Leveene, Stephanie, Springer US [mailto:Stephanie.Leveene@springer.com]
Sent: Tuesday, January 25, 2011 3:20 PM
To: Russell Portenoy, MD
Cc: Adams, Kate, Springer Healthcare
Subject: RE: Content for Purdue Opioid Resource CD-ROM: Text Files

Dear Dr. Portenoy,

Again, I apologize for the trouble you have had in opening the links. Have you been able to access the wireframe via the URL I e-mailed to you?

I will send you all of the pages via FedEx; they will be in the order they will appear on both the CD-ROM and the print version. The tracking number is 7966 9182 3628.

Sincerely,

Stephanie Leveene
Springer Healthcare LLC
Medical Writer

233 Spring Street | New York | NY 10013 | USA
tel: +1 212 460 1555
fax:+1 212 620 8442
mobile: +1 646 546 2361
E-mail: stephanie.leveene@springer.com

www.springerhealthcare.com

From: Russell Portenoy, MD [mailto:RPorteno@chpnet.org]
Sent: Tuesday, January 25, 2011 2:58 PM
To: Leveene, Stephanie, Springer US
Subject: RE: Content for Purdue Opioid Resource CD-ROM: Text Files

Dear Stephanie,

I am afraid that I am still having trouble with this. Some of these I could open, some not. I needed to reboot to be able to open them again. I did noticed that there is language in the ones that I could open that I would suggest revising. If you need a careful review, I am afraid that you will need to copy and fedex the pile to me. Is this still possible?

Thanks.

From: Leveene, Stephanie, Springer US [mailto:Stephanie.Leveene@springer.com]
Sent: Tuesday, January 18, 2011 11:37 AM
To: Russell Portenoy, MD
Subject: RE: Content for Purdue Opioid Resource CD-ROM: Text Files

Dear Dr. Portenoy,

Here are links to all of the pages. Please let me know if you have any questions.

Homepage: http://dl.dropbox.com/u/7223957/Homepage.docx

Section 1, Advisory Panel: http://dl.dropbox.com/u/7223957/Section%201.%20Advisory%20Panel.docx

Section 2, Recommendations: http://dl.dropbox.com/u/7223957/Section%202.%20Recommendations.docx

Section 3, Patient Evaluation Tools :
http://dl.dropbox.com/u/7223957/Section%203.%20Patient%20Evaluation%20Tools.docx
3A, Risk Assessment Tools:
http://dl.dropbox.com/u/7223957/Section%203A.%20Risk%20Assessment%20Tools.docx
3A-1, CAGE-AID Text Page: http://dl.dropbox.com/u/7223957/Section%203A-1.%20CAGE-AID.docx
3A-1, CAGE-AID Video Script: http://dl.dropbox.com/u/7223957/Section%203A-1%20Script.%20CAGE-AID.docx
3A-2, ORT Text Page: http://dl.dropbox.com/u/7223957/Section%203A-2.%20Opioid%20Risk%20Tool%20%28ORT%29.docx
3A-2, ORT Video Script: http://dl.dropbox.com/u/7223957/Section%203A-2%20Script.%20Opioid%20Resource%20Tool%20%28ORT%29.docx

3B, Patient Evaluation Tools:
http://dl.dropbox.com/u/7223957/Section%203B.%20Pain%20Inventory%20Tools.docx
3B-1, Brief Pain Inventory Text Page: http://dl.dropbox.com/u/7223957/Section%203B-1.%20Brief%20Pain%20Inventory.docx
3B-1, Brief Pain Inventory Video Script: http://dl.dropbox.com/u/7223957/Section%203B-1%20Script.%20Brief%20Pain%20Inventory.docx
3B-2, PADT Text Page: http://dl.dropbox.com/u/7223957/Section%203B-2.%20PADT.docx
3B-2, PADT Video Script: http://dl.dropbox.com/u/7223957/Section%203B-2%20Script.%20PADT.docx
3B-3, Simple Descriptive Pain Intensity Scale Text Page: http://dl.dropbox.com/u/7223957/Section%203B-3.%20Simple%20Descriptive%20Pain%20Intensity%20Scale.docx
3B-3, Simple Descriptive Pain Intensity Scale Video Script: http://dl.dropbox.com/u/7223957/Section%203B-3%20Script.%20Simple%20Descriptive%20Pain%20Intensity%20Scale.docx

Section 4, Case Vignettes: http://dl.dropbox.com/u/7223957/Section%204.%20Case%20Vignettes.docx
High-Risk Case 1: http://dl.dropbox.com/u/7223957/High-Risk%20Case%201--Script%20for%20Interactive%20Version.docx
High-Risk Case 2: http://dl.dropbox.com/u/7223957/High-Risk%20Case%202--Script%20for%20Interactive%20Version.docx
Moderate-Risk Case 1: http://dl.dropbox.com/u/7223957/Moderate-Risk%20Case%201--Script%20for%20Interactive%20Version.docx

Moderate-Risk Case 2: http://dl.dropbox.com/u/7223957/Moderate-Risk%20Case%202--Script%20for%20Interactive%20Version.docx
Low-Risk Case 1: http://dl.dropbox.com/u/7223957/Low-Risk%20Case%201--Script%20for%20Interactive%20Version.docx
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6B, Patient Informed Consent Text Page:
http://dl.dropbox.com/u/7223957/Section%206B.%20Patient%20Informed%20Consent.docx
6B, Patient Informed Consent Video Script:
http://dl.dropbox.com/u/7223957/Section%206B%20Script.%20Patient%20Informed%20Consent.docx
6C, Urine Toxicology Screen and Medication Counts:
http://dl.dropbox.com/u/7223957/Section%206C.%20Urine%20Toxicology%20Screen%20and%20Medication%20Counts.docx

Section 7, Patient Education: http://dl.dropbox.com/u/7223957/Section%207.%20Patient%20Education.docx
7A, Drug Storage and Sharing:
http://dl.dropbox.com/u/7223957/Section%207A.%20Drug%20Storage%20and%20Sharing.docx
7B, Drug Disposal and Destruction:
http://dl.dropbox.com/u/7223957/Section%207B.%20Drug%20Disposal%20and%20Distruction.docx
7C, Adverse Events: http://dl.dropbox.com/u/7223957/Section%207C.%20Adverse%20Events.docx

Section 8, Additional Resources: http://dl.dropbox.com/u/7223957/Section%208.%20Additional%20Resources.docx

---

From: Russell Portenoy, MD [mailto:RPorteno@chpnet.org]
Sent: Tuesday, January 18, 2011 10:50 AM
To: Leveene, Stephanie, Springer US
Cc: Adams, Kate, Springer Healthcare
Subject: RE: Content for Purdue Opioid Resource CD-ROM: Text Files

Thank you. The internet links would work I think.

From: Leveene, Stephanie, Springer US [mailto:Stephanie.Leveene@springer.com]
Sent: Tuesday, January 18, 2011 8:58 AM
To: Russell Portenoy, MD
Cc: Adams, Kate, Springer Healthcare
Subject: RE: Content for Purdue Opioid Resource CD-ROM: Text Files
Importance: High

Dear Dr. Portenoy,

I'm sorry you are having trouble with the zip file. I think it may be easier for me to print out everything and send them to you as hard copy, via Fed Ex. Alternately, I can copy them all into my Dropbox folder and send you an e-mail with individual Internet links to each file. Which would be best for you?

Sincerely,

Stephanie Leveene
Springer Healthcare LLC
Medical Writer

233 Spring Street | New York | NY 10013 | USA
tel: +1 212 460 1555
fax:+1 212 620 8442
mobile: +1 646 546 2361
E-mail: stephanie.leveene@springer.com

www.springerhealthcare.com

From: Russell Portenoy, MD [mailto:RPorteno@chpnet.org]
Sent: Tuesday, January 18, 2011 7:30 AM
To: Leveene, Stephanie, Springer US
Cc: Adams, Kate, Springer Healthcare
Subject: RE: Content for Purdue Opioid Resource CD-ROM--for your review

I am sorry but I am unable to open this zip file. There is an error message when I try to do so. Can you send it a different way?

From: Leveene, Stephanie, Springer US [mailto:Stephanie.Leveene@springer.com]
Sent: Tuesday, January 11, 2011 1:22 PM
To: Russell Portenoy, MD
Cc: Adams, Kate, Springer Healthcare
Subject: Content for Purdue Opioid Resource CD-ROM--for your review

Dear Dr. Portenoy,

I hope your new year has been going well so far. I'm writing to follow up on Kate Adams' note of December 16, 2010, regarding the next steps for the Purdue Opioid Resource project. Per her note, the draft content for the resource is attached for your review. This content can be broken down as follows:

- Plain text for the pages where there will be no interactivity
- Scripts for the several short videos that will explain how to use each featured tool and discuss staff education and patient informed consent. Once these scripts have been reviewed and updated, there will be a separate discussion as to which thought leader will narrate (and appear) on which video.
- Scripts for the interactive case studies. There are 6 cases: 2 each for low-, moderate-, and high-risk patients. We have designed these to be engaging to the user, with animated forms and questions about treatment (though the user will not be asked to pick an answer), and weaving in messages based on your 4 questions.

We would like to have your thoughts on these documents by **Monday, January 24**. Please don't hesitate to contact me or Kate Adams if you have any questions in the meantime. Purdue is very excited about this new, interactive format for the Opioid Resource, and we are looking forward to working with you on it in 2011.

Russell Portenoy, MD

From: Adams, Kate, Springer Healthcare [Kate.Adams@springer-sbm.com]
Sent: Tuesday, February 01, 2011 1:37 PM
To: pchristo@jhmi.edu; passiks@mskcc.org; ArGoffC@mail.amc.edu; cargoff@nycap.rr.com; Russell Portenoy, MD
Cc: osir@MSKCC.ORG; Donna Reid; Leveene, Stephanie, Springer US; Braca, David, Springer US
Subject: Purdue Risk Assessment Resource (Videos)_Telecon Request

Dear All

I hope this email finds you all well and the first month of 2011 has been fruitful.

As a follow-up to the emails that Stephanie Leveene sent last month regarding the content, we would now like to focus on the script/video elements (as listed below), and in particular ascertain which ones you would like to present.

Section 3A-1 Script. CAGE-AID
Section 3A-2 Script. Opioid Resource Tool (ORT)
Section 3B-1 Script. Brief Pain Inventory
Section 3B-2 Script. PADT
Section 3B-3 Script. Simple Descriptive Pain Intensity Scale
Section 6A: Staff Education
Section 6B: Patient Informed Consent

We wish to schedule a teleconference with you all together to reach a consensus on who should do which video. In this TC we can also discuss any comments on the other content reviewed. We would like to hold the conference, if possible, next week (week commencing 7th February).

At your earliest convenience, please let me know of a few dates and times that would be suitable for you, and from this I will try to find a date and time that you can all do. The call should last no longer than 40 minutes.

I look forward to hearing from you.

Kind regards
Kate

Kate Adams

Springer Healthcare Ltd

Account Manager

Farside House | Nantwich Road | Tarporley | Cheshire | CW6 9UY | UK

Telephone: +44 (0)1829 731240

Mobile: +44 (0) 7961 422621

Fax: +44 (0)1829 732772
E-mail: kate.adams@springer.com

Russell Portenoy, MD

From: Leveene, Stephanie, Springer US [Stephanie.Leveene@springer.com]
Sent: Monday, February 07, 2011 8:54 AM
To: Russell Portenoy, MD
Cc: Donna Reid; Adams, Kate, Springer Healthcare
Subject: Comments on Opioid Resource text

Dear Dr. Portenoy,

Thank you very much for your comments on the Opioid Resource text that I sent you; I found the documents in my mailbox this morning. One note: I apologize for not mentioning this when I sent the materials, but the "General Safety Information on Opioids" text that will appear on the homepage is required language from Purdue and cannot be changed or deleted in any way.

I look forward to speaking with you on Thursday.

Sincerely,

Stephanie Leveene
Springer Healthcare LLC
Medical Writer

233 Spring Street | New York | NY 10013 | USA
tel: +1 212 460 1555
fax:+1 212 620 8442
mobile: +1 646 546 2361
E-mail: stephanie.leveene@springer.com

www.springerhealthcare.com

Russell Portenoy, MD

From: Leveene, Stephanie, Springer US [Stephanie.Leveene@springer.com]
Sent: Thursday, February 10, 2011 2:23 PM
To: Russell Portenoy, MD
Cc: Adams, Kate, Springer Healthcare; Braca, David, Springer US
Subject: Follow-up to call re: Opioid Resource videos
Attachments: Opioid Resource Videos.pptx; High-Risk Case 2--Script for Interactive Version.docx

Dear Dr. Portenoy,

Thank you for participating in our conference call today. As a follow-up, attached please find the PowerPoint presentation that was displayed during the call, which includes a list of all of the video elements; (b) what the patient vignettes and instructional videos will be comprised of; and (c) sample scripts. Please let us know if you have a preference as to which videos you would like to narrate/appear on. I am also attaching a copy of the high-risk case that we have rewritten. If you would like to review the other 12 scripts, please let us know the best way to send these to you.

Once the assignments for the videos have been made, we will be in touch to schedule a video shoot and audio recording at your convenience.

If you have any questions, please don't hesitate to contact me, David Braca, or Kate Adams. Thank you very much for your help with this, and again for your participation on this project.

Sincerely,

Stephanie Leveene
Springer Healthcare LLC
Medical Writer

233 Spring Street | New York | NY 10013 | USA
tel: +1 212 460 1555
fax:+1 212 620 8442
mobile: +1 646 546 2361
E-mail: stephanie.leveene@springer.com

www.springerhealthcare.com

Russell Portenoy, MD

From: Russell Portenoy, MD
Sent: Tuesday, February 15, 2011 6:15 AM
To: 'Leveene, Stephanie, Springer US'
Cc: Adams, Kate, Springer Healthcare; Braca, David, Springer US
Subject: RE: Videos for Purdue Opioid Resource

This is fine.
Thanks.

From: Leveene, Stephanie, Springer US [mailto:Stephanie.Leveene@springer.com]
Sent: Monday, February 14, 2011 2:05 PM
To: Russell Portenoy, MD
Cc: Adams, Kate, Springer Healthcare; Braca, David, Springer US
Subject: RE: Videos for Purdue Opioid Resource

Dear Dr. Portenoy,

Thank you for your note. What we have left is one of the low-risk cases, the Simple Pain Intensity Scale video, and the Staff Education video. Would you be OK with those?

Also, please let me know if you have any changes to the revised high-risk case (Ben). Thank you very much.

Sincerely,

Stephanie Leveene
Springer Healthcare LLC
Medical Writer

233 Spring Street | New York | NY 10013 | USA
tel: +1 212 460 1555
fax:+1 212 620 8442
mobile: +1 646 546 2361
E-mail: stephanie.leveene@springer.com

www.springerhealthcare.com

From: Russell Portenoy, MD [mailto:RPorteno@chpnet.org]
Sent: Monday, February 14, 2011 1:31 PM
To: 'pchristo@jhmi.edu'; Leveene, Stephanie, Springer US
Cc: Adams, Kate, Springer Healthcare; Braca, David, Springer US
Subject: Re: Videos for Purdue Opioid Resource

Whatever is left is fine. Thank you

From: Paul Christo <pchristo@jhmi.edu>
To: Leveene, Stephanie, Springer US <Stephanie.Leveene@springer.com>; Russell Portenoy, MD
Cc: Adams, Kate, Springer Healthcare <Kate.Adams@springer-sbm.com>; Braca, David, Springer US <David.Braca@springer.com>

Sent: Mon Feb 14 11:13:01 2011
Subject: RE: Videos for Purdue Opioid Resource

HI,

- I'll take CAGE-AID, Patient Informed Consent, high risk case.

Thanks,
paul

Paul J. Christo, MD., MBA
Assistant Professor
Director, Multidisciplinary Pain Fellowship Program
Department of Anesthesiology and Critical Care Medicine
Division of Pain Medicine
Johns Hopkins University School of Medicine
550 North Broadway, Suite 301
Baltimore, MD 21205
(410) 955-1818 Phone
(410) 502-6730 Fax

From: Leveene, Stephanie, Springer US [mailto:Stephanie.Leveene@springer.com]
Sent: Monday, February 14, 2011 9:30 AM
To: Paul Christo; Russell Portenoy, MD
Cc: Adams, Kate, Springer Healthcare; Braca, David, Springer US
Subject: Videos for Purdue Opioid Resource

Dear Dr. Christo and Dr. Portenoy,

I wanted to follow up on our Thursday call and the e-mail I sent you regarding the videos for the Purdue Opioid Resource. Dr. Argoff has gotten back to us regarding his preferences, and he has decided to narrate/appear on the ORT video, the Brief Pain Inventory video, one of the low-risk cases, and one of the high-risk cases.

These are the videos that are still available:

- CAGE-AID
- PADT
- Simple Descriptive Pain Intensity Scale
- Staff Education
- Patient Informed Consent
- 1 low-risk case
- 2 moderate-risk cases
- 1 high-risk case

Please let us know if you have any preferences among these. If not, we will randomly assign 3 scripts to you (a mix of cases and training videos). Thank you very much for your help with this.

Sincerely,

Stephanie Leveene

Russell Portenoy, MD

From: Etchells, Katy, Springer Healthcare [Katy.Etchells@springer-sbm.com]
Sent: Wednesday, May 04, 2011 10:01 AM
To: Russell Portenoy, MD
Cc: Braca, David, Springer US; Leveene, Stephanie, Springer US
Subject: PERFORM Update

Dear Dr. Portenoy,

Please allow me to introduce myself. My name is Katy Etchells and I am a Senior Account Manager at Springer Healthcare. I am writing to you regarding the PERFORM project that you have been working on with my colleague Kate Adams. There has been an internal project management change for PERFORM, and I will now be managing this project from the US office along with the existing team of Stephanie Leveene and David Braca.

I am writing to update you on the latest developments of the PERFORM project. It is currently with Purdue for Medical Legal review, and we hope to hear back from them in the coming weeks. The next stage of the process will be for us to start the video filming. Can you please let us know if you have any commitments in May/June/July that we would need to know about in advance so we know what dates to avoid when looking at the schedules for filming?

Thank you again for all your support to date. We look forward to speaking with you again soon.

Kind Regards
Katy

Katy Etchells
Springer Healthcare Ltd
Senior Account Manager

Farside House | Nantwich Road | Tarporley | Cheshire | CW6 9UY | UK
tel: +44 (0)1829 731244
mobile: +44 (0)7917 451070
fax: +44 (0)1829 732772
---
233 Spring St | New York | NY | 10013 | USA
tel: +1 212 257 5212

E-mail: katy.etchells@springer.com
---
www.springerhealthcare.com

Russell Portenoy, MD

From: Etchells, Katy, Springer Healthcare [Katy.Etchells@springer-sbm.com]
Sent: Monday, June 06, 2011 4:58 PM
To: Donna Reid
Cc: Russell Portenoy, MD
Subject: RE: PERFORM Update

Dear Donna,

Further to my email below, please could you also let me know what availability Dr Portenoy has next week too. We are trying to find a suitable time when all of the key thought leaders involved is this project will be available to have a telecon together.

Many thanks and kind regards
Katy

Katy Etchells
Springer Healthcare Ltd
Senior Account Manager

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fax: +44 (0)1829 732772
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tel: +1 212 257 5212

E-mail: katy.etchells@springer.com
---
www.springerhealthcare.com

From: Etchells, Katy, Springer Healthcare
Sent: 03 June 2011 19:12
To: DoReid@chpnet.org
Cc: RPorteno@chpnet.org
Subject: FW: PERFORM Update
Importance: High

Donna,

Please can you help with the request below?

Kind Regards
Katy

Katy Etchells
Springer Healthcare Ltd

Senior Account Manager

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fax: +44 (0)1829 732772
---
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tel: +1 212 257 5212

E-mail: katy.etchells@springer.com
---
www.springerhealthcare.com

From: Etchells, Katy, Springer Healthcare
Sent: 03 June 2011 19:11
To: RPorteno@chpnet.org
Cc: Leveene, Stephanie, Springer US; Braca, David, Springer US
Subject: PERFORM Update
Importance: High

Dear Dr. Portenoy,

Further to our meeting with Purdue today on the PERFORM initiative. There have been a couple of issues raised by them which we would like to discuss further with you and the other thought leaders involved in this project.

Please can you advise us on what availability you have during the next week or so to have a short teleconference to discuss further.

Many thanks and kind regards,

Katy

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Springer Healthcare Ltd
Senior Account Manager

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